

### REMARKS

Entry of the above amendments and reconsideration of this application are requested. Upon entry of the amendments, this application will contain claims 27-46, 48-54 and 64-66 pending and under consideration. Claims 47 and 67-70 have been cancelled without admission or prejudice. Claims 27 and 45 have been amended. Support for these amendments is found, for example, at page 11, line 22 (oxidizing disinfecting agent) and page 15, lines 9-14 (separating attached tunica muscularis tissue from the submucosa tissue). Claim 31 has been amended (liquid medium containing the disinfecting agent). Support for this amendment is found for example at page 11, lines 24-25. Claim 48 has been formally amended to change its dependency to claim 46, due to the cancellation of claim 47 from which it previously depended. The amendments introduce no new subject matter and their entry is solicited. It is believed that the above amendments and the following remarks address all issues remaining from the office action. Allowance of the application is therefore solicited.

#### **Continued Examination under 37 C.F.R. 1.114**

The acknowledgement of the present request for continued examination is noted. In addition, the undersigned attorney apologizes for the inadvertent omissions in not pointing out specific support in the application for the amendments in the prior response, and in not responding to the request for identification of certain co-pending applications.

#### **Elections/Restrictions**

The Examiner's withdrawal of claims 68-70 from consideration as being directed to a non-elected invention is noted. Those claims have been cancelled without prejudice to pursuit of those claims in a divisional or other related application.

#### **Specification**

The Office Action indicates a need for a correction of the continuing data. The above-made amendment corrects the continuing data. In addition, the Action noted a need to document the filing of an extension of time in the parent application to establish co-pendency with the parent application. In response, attached is a true and accurate copy of the request for extension as filed in the parent application

and as maintained in the undersigned's files. Co-pendency was present, and favorable indication is solicited in this regard.

#### **Claim rejections 35 U.S.C. 102**

Claims 27-66 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cook, et al. US 6,206,931. As established above, the present application properly claims priority to and through the '931 patent. Accordingly, the present claims have a priority date at least as early as the filing date of the '931 patent. The '931 patent is not prior art to the present application, and withdrawal of this rejection is solicited.

Claims 27, 28, 31-34 and 45-49 stand rejected under 35 U.S.C. 102(b) as being anticipated by McCusker, US 3,649,163. This rejection is respectfully traversed because McCusker fails to teach all elements of the rejected claims. In particular, claim 27 and claims dependant thereon require removing the collagen-based matrix comprising submucosa from the disinfected submucosa tissue source, said removing including separating amounts of the attached tunica muscularis tissue from the submucosa". While the McCusker reference describes that some muscle tissue can be left attached to the serosa or submucosa tissue after the prior mechanical separation from the bulk of

the intestine, this reference fails entirely to teach the separation of that muscle tissue from the serosa or submucosa following treatment with a disinfecting agent to provide a disinfected material. Claim 45 and its dependent claims include a limitation of similar nature. For these reasons, withdrawal of the rejection under 35 U.S.C. 102(b) over McCusker is solicited.

#### Claims Rejections 35 U.S.C. 103

Claims 27-54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak, et al, US 5,695,998 in view of McCusker, US 3,649,163 and O'Leary, US 5,298,222 or Kemp, US 5,460,962. For the reasons discussed below, this rejection is respectfully traversed.

The Examiner contends that Badylak '998 teaches delaminating and then disinfecting a submucosal tissue source, that McCusker teaches that separation of submucosa from intestine leaves some remaining tunica muscularis, and that O'Leary or Kemp teaches "further mechanical processing" of tissue after it is disinfected. From these teachings, the Examiner takes the position that "it would have been prima facie obvious to disinfect the submucosal tissue source of Badylak

prior to delamination for the same reason that O'Leary does the same".

O'Leary fails to provide anything that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of the rejected claims, with or without any additional knowledge imparted by McCusker or Kemp. As noted by the Examiner, Badylak '998 teaches disinfection after isolation of the submucosal tissue. With regard to disinfection, O'Leary teaches only that "After the bone has been shaped, it is treated with a disinfectant in order to kill vegetative organisms".

Col. 1, lines 29-30. This is fully consistent with the post-isolation treatment of Badylak '998 and of McCusker and Kemp.

While O'Leary teaches the use of a soak of musculoskeletal tissue in an antibiotic prior to transport (Col. 1, lines 18-19) this does not in any teach or suggest treating a submucosal tissue source such as that disclosed in Badylak '998 with an oxidizing disinfecting agent, and then removing a collagen based matrix including separation of tunica muscularis tissue from submucosa tissue.

Further in this regard, as disclosed in the application, treatment of the submucosal tissue source prior to removal of the collagen based matrix provides several advantages which could not have been expected prior to the applicants' discovery.

The claimed processes provide recovered matrices with very low endotoxin levels (see specific Examples), and also lead to greater ease in removing attached tissues from the submucosa layer (see e.g. page 11, lines 16-17 and page 15, lines 12-14), collagen based matrices with less attached tissue and debris on the surface (page 15, lines 14-16), and more uniform matrices from one processing run to another (page 15, lines 19-22). None of these unexpected advantages are disclosed in Badylak '998, O'Leary, McCusker or Kemp, or any combination thereof. These unexpected results further buttress that the claims are patentably distinct from the combination of references relied upon, as it is well established that the claimed invention must be considered as a whole, including advantages flowing therefrom.

For at least these reasons, the rejected claims are not rendered obvious by Badylak '998 in view of McCusker and O'Leary or Kemp. Reconsideration and withdrawal of this rejection is thus solicited.

Claims 64-66 stand rejected under 35 U.S.C. 103(a) as obvious over Badylak et al. (US 5,695,998) or Abraham et al. (U.S. 5,993,844) in view of Badylak (US 5,554,389) and O'Leary

(US 5,298,222) or Kemp (US 5,460,962). This rejection is traversed for the following reasons.

It is well established that for a proper rejection under 35 U.S.C. 103, the reference or combination of references must teach all elements of the claim. Process claims 64-66 require recovering a collagen-containing matrix that comprises submucosa tissue and lamina propria tissue in combination with the other claimed features. None of the cited references teaches such an embodiment, and the Office Action does not substantively address how this element was reached based on the reference combination. Withdrawal of the rejection is thus solicited.

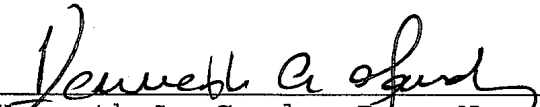
In response to the Examiner's request regarding copending applications, the applicants would like to bring the priority related applications listed below (with accompanying publication number) to the Examiner's attention. Each of these applications, including claims, should be available in IFW image format and/or as published. Nonetheless, if the Examiner would like copies provided, or would like to discuss any of these applications, please contact the undersigned attorney.

11/931,884 (US 20080213335)  
11/931,638 (US 20080171092)  
11/932,000 (US 20080167728)  
11/931,743 (US 20080167727)

11/931,638 (US 20080145397)  
11/931,556 (US 20080145395)  
10/744,420 (US 20040137042)

In view of the foregoing amendments and remarks,  
reconsideration and allowance of this application containing  
claims 27-46, 48-54, and 64-66 is requested. The Examiner is  
requested to contact the undersigned attorney by telephone to  
arrange an interview if the Examiner believes that there are any  
remaining rejections or objections preventing allowance of this  
application.

Respectfully submitted,

By   
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## PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional)  
3433-282**COPY**

In re Application of Cook et al.

Application Number 09/798,441

Filed March 2, 2001

For GRAFT PROSTHESIS, MATERIALS AND METHODS

Art Unit

Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☐ One month (37 CFR 1.17(a)(1)) \$ \_\_\_\_\_
- ☐ Two months (37 CFR 1.17(a)(2)) \$ \_\_\_\_\_
- ☒ Three months (37 CFR 1.17(a)(3)) \$ 950
- ☐ Four months (37 CFR 1.17(a)(4)) \$ \_\_\_\_\_
- ☐ Five months (37 CFR 1.17(a)(5)) \$ \_\_\_\_\_

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: \$ \_\_\_\_\_.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 23-3030.

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number: 33,386

☐ attorney or agent under 37 CFR 1.34(a).  
Registration number if acting under 37 CFR 1.34(a): \_\_\_\_\_

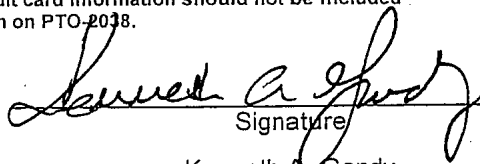
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

March 26, 2004

Date

(317) 634-3456

Telephone Number



Signature

Kenneth A. Gandy

Typed or printed name

Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. see below.

☐ Total of \_\_\_\_\_ forms are submitted

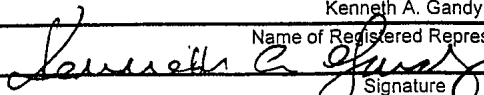
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Service" EV432598232US in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on:

March 26, 2004

(Date of Deposit)

Kenneth A. Gandy

Name of Registered Representative



Signature

Date of Signature: March 26, 2004